UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
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STATEMENT OF COMMISSIONER ANNE M. NORTHUP ON THE PETITION REQUESTING AN EXCEPTION FROM THE LEAD CONTENT LIMITS: ERTL SCALE MODELS AND DYERSVILLE DIE CAST

April 5, 2012

I write to applaud the unanimous vote to grant an exception to the 100 ppm lead content limit for certain children's ride-on pedal tractor component parts made with aluminum alloys. The vote represents a watershed moment in the Consumer Product Safety Commission's approach to the regulation of lead in the metal substrate of children's products. It establishes for the first time bipartisan acceptance, based on the expert advice of CPSC's professional staff, of the principles that (1) lead in children's products presents a risk of harm only to the extent that children are exposed to the lead; and (2) metal substrate containing 300 ppm of lead that is not likely to be placed in the mouth, ingested, or *extensively* contacted by children does not present a health risk, because it does not measurably increase blood lead levels. Based on these conclusions, I believe a wide range of additional products should be similarly excepted from the 100 ppm lead content limit. I therefore encourage product manufacturers to petition for relief, and urge my fellow Commissioners to support me in exercising our authority to initiate additional exceptions as appropriate.

Staff's determination that no measurable increase in blood lead level would result from a child's exposure to certain aluminum alloy components of a ride on tractor containing 300 ppm of lead was not a close call. Staff has conducted extensive wipe-testing of metal jewelry items and vinyl bibs containing far more lead – up to 100,000 ppm (equivalent to 10 percent lead), and these tests resulted in average lead transfers per wipe of less than 0.02 micrograms of lead. *See* Staff Briefing Package: Request for Exception from CPSIA Section 101(a) lead content limit for Pedal Tractors from Joseph L. Ertl, Inc., Scale Models of Dyersville Die Cast Divisions (March 21, 2001) ("Ertl Briefing Package") at 30. Based on "[e]xtensive scientific literature and several physiologic models" describing the relationship between exposure and blood lead level, staff estimated that even exposure to as much as 1.2 micrograms per day, in *addition* to default inputs for lead from sources such as diet and soil, does not result in a measurable increase in the blood lead level of children ages 3-7 years. *Id.* at 31. Staff further estimated that a child could have between no contacts and several contacts with a ride on pedal tractor on any given day. *Id.* at 31-32. Thus, even using an average per wipe exposure of materials having far more lead than the component parts at issue here, and the relatively high number of 60 contacts per day (1.2/.02 = 60), there would still be no measurable increase in blood lead levels, and therefore no adverse impact on public health or safety.

Notably, Ertl also satisfied the other criteria for the grant of an exception to the 100 ppm lead content limit, based on circumstances that are likely present in connection with many other products containing lead in metal substrate. The CPSC has authority to except from the 100 ppm lead content limit a product, class of product, material, or component part that, in addition to not resulting in a measurable increase in the blood lead level of a child: (1) requires the inclusion of lead because it is not *practicable* or not technologically feasible to manufacture it by removing excessive lead or by making the lead inaccessible; and (2) is not likely to placed in the mouth or ingested. 15 U.S.C. § 1278a(b)(1)(A)(i)-(iii).

Practicability is evaluated on a case-by-case basis taking into account a number of factors, including the utility of the substitute material, the availability of materials with less than 100 ppm lead, relative cost, inaccessibility considerations, conformity assurance and technological feasibility. Ertl Briefing Package at 2, n. 1. The CPSC concluded that it was not practicable for Ertl to manufacture the pedal tractor components using aluminum alloy with 100 ppm of lead, in part because the minimum quantity available for purchase represented a seven year supply at Ertl's rate of manufacture, and would require about 15% of the company's yearly sales to purchase it. Ertl Briefing Package at 13. Other materials, such as plastic, zinc or steel were determined not to be practicable, because they would either change the "appearance" of the product, result in a much heavier product, or require Ertl to invest in new metal stamping technology and training, which would increase the per unit production cost. Ertl Briefing Package at 3. Staff had a choice between recommending that Ertl be required to use aluminum alloy containing 200 ppm or 300 ppm of lead, both of which were equally attainable in the quantities needed. Staff concluded that 300 ppm was practicable, because the 200 ppm alloy would increase manufacturing costs by 1% over that of the 300 ppm alloy. *Id.* Making the aluminum alloy inaccessible by introducing a covering was deemed not practicable because it "would represent a change in [the] current manufacturing process." *Id.*

While practicability must be assessed on a case-by-case basis, several important principals can be gleaned from staff's approach to the Ertl petition. First, a petitioner may be entitled to retain the current appearance of a product for "aesthetic" reasons, i.e., metal vs. plastic, if its customers prefer it. *Id.* Indeed, significant differences in "general appeal to consumers" can support considering a model made with a different material to be a "different product." *Id.* at 20. In addition, a petitioner need not undermine the functionality of the product in order to reduce its lead content, by, for instance, increasing its weight to an extent that impedes maneuverability. The Ertl case also highlights the importance of cost differentials. The fact that introduction of a new material would increase the cost of manufacture by necessitating a change in the manufacturing process was a factor in favor of granting the petition. Indeed, even a 1% increase in total manufacturing cost justified favoring aluminum alloy with 300 ppm of lead over aluminum alloy with 200 ppm of lead. The accessibility of an alternative with less lead is also key, and in that regard, the mere fact that a market exists does not warrant a finding of practicability. As the Ertl case demonstrates, the need to warehouse amounts in excess of that needed for ongoing manufacturing purposes also weighs against a finding of practicability.

With regard to the likelihood that a component will be placed in the mouth or ingested, the size and location of the component are central considerations. So long as the component is too large to be ingested or placed in the mouth, the only route of lead exposure is through hand to mouth activity. And as staff's health sciences experts concluded, components containing 300 ppm of lead in metal substrate that are not "extensively contacted by children" do not expose children to sufficient lead through hand to mouth contact to measurably increase blood lead levels. *See* Draft *Federal Register* Notice – Petition Requesting Exception from Lead Content Limits; Notice Granting Exception (as amended March 30, 2012) at 5. Notably, in the case of the Ertl ride on tractor, this included the main body casting, which CPSC's human factors experts determined was the component most likely to be touched by a child playing on the tractor. Ertl Briefing Package at 26.

Based on staff's analysis of the Ertl petition and the principles that can be derived from it, there are other candidates for potential exception. These include: tricycles, scooters, certain sporting equipment, hobby horses, pogo sticks, and skate boards, just to name a few that come readily to mind.

While I am pleased that the functional purpose exception included with the 2011 amendments to the Consumer Product Safety Improvement Act may have greater utility than I feared, recognition of these principles comes too late and at far greater cost than was necessary. As originally enacted, the CPSIA permitted the Commission to exclude from the reduced lead limits products that would neither "result in the absorption of any lead into the human body, taking into account normal and reasonably foreseeable use and abuse of such product by a child," nor have any other adverse impact on health or safety. CPSIA § 101(b)(1). It is clear from staff's conclusion in the Ertl case that many product components containing 300 ppm – or even 600 ppm -- of lead in metal substrate that are too large to be ingested or placed in the mouth would not result in the *measurable* absorption of any lead. Yet the Commission determined in 2008 that the absorbability exclusion could never be satisfied by any material, product or component. During the succeeding three years, many businesses that might satisfy the criteria applied in Ertl under the new functional purpose exception have closed, substantially reduced their product line, or compromised the durability or functionality of their products, because they could not practicable reduce the lead in their products, despite the fact that the products presented no risk of meaningful lead exposure.

The Ertl petition vote similarly highlights the unnecessary economic harm caused by the Commission's party-line vote to reduce the lead standard to 100 ppm based on the questionable conclusion that there is no product, class of products, materials or components for which it is not "technologically feasible" to do so. Most obviously, the conclusion was reached for aluminum alloy, which we now know does not present a risk of harm to children at 300 ppm of lead when used in larger component parts. The testing that underlies staff's conclusion that such aluminum alloy is not a health risk could support the same finding for other metal substrate containing 300 ppm of lead when used in a component that is not ingestible or able to be placed in the mouth. But instead of

adopting a blanket exception, the Commission has left it to individual manufacturers to bear the expense and delay of petitioning the Commission for relief.

In conclusion, I applaud the Commission's decision to finally recognize that certain components of children's products containing 300 ppm of lead in metal substrate do not present a risk of harm because they do not *expose* children to sufficient lead to measurably increase blood lead levels. I hope that this milestone decision invites additional petitions and inspires the Commission to independently consider other opportunities to alleviate the unnecessary economic harm caused by its 100 ppm decision. I only wish the rational approach represented by the Commission's adoption of staff's analysis of the Ertl petition had prevailed sooner.